OSIRIS THERAPEUTICS, INC.
Form 10-Q
August 09, 2012
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended June 30, 2012**

**Or**

**o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from to**

**Commission File Number: 001-32966**

# OSIRIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

| **Maryland** | **71-0881115** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **7015 Albert Einstein Drive, Columbia, Maryland** | **21046** |
| (Address of principal executive offices) | (Zip Code) |

**443-545-1800**

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

| Large accelerated filer o | Accelerated filer x |
|---|---|
| Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company o |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

| **Class** | **Outstanding at August 3, 2012** |
|---|---|
| Common Stock, par value $0.001 per share | 32,868,021 |

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**PART I FINANCIAL INFORMATION**

**Item 1. Financial Statements - Unaudited**

**OSIRIS THERAPEUTICS, INC.**

**CONDENSED BALANCE SHEETS**

**(amounts in thousands, except per share amounts)**

| | June 30, 2012 (unaudited) | December 31, 2011 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash | $ 1,109 | $ 1,661 |
| Investments available for sale | 37,637 | 45,604 |
| Accounts receivable, net | 1,393 | 728 |
| Inventory | 475 | 767 |
| Deferred tax asset | | 2,188 |
| Prepaid expenses and other current assets | 3,371 | 470 |
| Total current assets | 43,985 | 51,418 |
| | | |
| Property and equipment, net | 2,153 | 2,463 |
| Restricted cash | 392 | 392 |
| Total assets | $ 46,530 | $ 54,273 |
| | | |
| **Liabilities and Stockholders Equity** | | |
| | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 5,166 | $ 4,692 |
| Deferred revenue, current portion | | 3,333 |
| Total current liabilities | 5,166 | 8,025 |
| | | |
| Other long-term liabilities | 405 | 430 |
| Total liabilities | 5,571 | 8,455 |
| | | |
| Stockholders equity | | |
| Common stock, $.001 par value, 90,000 shares authorized, 32,868 shares outstanding - 2012, 32,828 shares outstanding - 2011 | 33 | 33 |
| Additional paid-in-capital | 278,785 | 278,092 |
| Accumulated other comprehensive income | 5 | 20 |
| Accumulated deficit | (237,864) | (232,327) |
| Total stockholders equity | 40,959 | 45,818 |
| Total liabilities and stockholders equity | $ 46,530 | $ 54,273 |

The accompanying notes are an integral part of these condensed financial statements.

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**OSIRIS THERAPEUTICS, INC.**

**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME**

**Unaudited**

**(amounts in thousands, except per share data)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2012** | **2011** | **2012** | **2011** |
| **Product revenues** | $ 1,626 | $ 130 | $ 2,763 | $ 167 |
| Cost of product revenues | 552 | 55 | 939 | 70 |
| Gross profit | 1,074 | 75 | 1,824 | 97 |
| **Revenue from collaborative research agreements and royalties** | 98 | 10,224 | 3,544 | 20,619 |
| Operating expenses: | | | | |
| Research and development | 4,072 | 5,209 | 8,035 | 9,920 |
| General and administrative | 1,418 | 3,280 | 2,941 | 4,976 |
| | 5,490 | 8,489 | 10,976 | 14,896 |
| (Loss) income from operations | (4,318) | 1,810 | (5,608) | 5,820 |
| Other income, net | 21 | 25 | 39 | 54 |
| (Loss) income before income taxes | (4,297) | 1,835 | (5,569) | 5,874 |
| Income tax benefit (expense) | 32 | (43) | 32 | (43) |
| **Net (loss) income** | (4,265) | 1,792 | (5,537) | 5,831 |
| Other comprehensive income | | | | |
| Unrealized gain (loss) on investments available for sale | 1 | 22 | (15) | 34 |
| **Total comprehensive (loss) income** | $ (4,264) | $ 1,814 | $ (5,552) | $ 5,865 |
| Basic (loss) earnings per share | $ (0.13) | $ 0.05 | $ (0.17) | $ 0.18 |
| Diluted (loss) earnings per share | $ (0.13) | $ 0.05 | $ (0.17) | $ 0.18 |
| Weighted average common shares (basic) | 32,860 | 32,821 | 32,845 | 32,814 |
| Weighted average common shares (diluted) | 32,860 | 33,134 | 32,845 | 33,124 |

The accompanying notes are an integral part of these condensed financial statements.

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**OSIRIS THERAPEUTICS, INC.**

**CONDENSED STATEMENT OF STOCKHOLDERS EQUITY**

**For the six months ended June 30, 2012**

**Unaudited**

**(amounts in thousands, except for share and per share data)**

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance at January 1, 2012** | **32,827,521** | **$ 33** | **$ 278,092** | **$ 20** | **$ (232,327)** | **$ 45,818** |
| Exercise of options to purchase common stock ($0.40 per share) | 15,500 | | 6 | | | 6 |
| Share-based payment-director services ($5.08 per share) | 25,000 | | 127 | | | 127 |
| Share-based payment-employee compensation | | | 560 | | | 560 |
| Net loss | | | | | (5,537) | (5,537) |
| Unrealized loss on investments available for sale | | | | (15) | | (15) |
| **Balance at June 30, 2012** | **32,868,021** | **$ 33** | **$ 278,785** | **$ 5** | **$ (237,864)** | **$ 40,959** |

The accompanying notes are an integral part of these condensed financial statements.

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**OSIRIS THERAPEUTICS, INC.**

**CONDENSED STATEMENTS OF CASH FLOWS**

**Unaudited**

**(amounts in thousands)**

| | Six months ended, June 30, | |
|---|---|---|
| | **2012** | **2011** |
| **Cash flows from operating activities:** | | |
| Net (loss) income | $ (5,537) | $ 5,831 |
| **Adjustments to reconcile net (loss) income to net cash used in operating activities:** | | |
| Depreciation and amortization | 348 | 375 |
| Non cash share-based payments | 687 | 994 |
| Provision for bad debts | 11 | |
| Non cash expense- extension of expiration date of warrant to related party | | 1,740 |
| **Changes in operating assets and liabilities:** | | |
| Accounts receivable, net | (676) | 1,263 |
| Inventory, prepaid expenses, and other current assets | (421) | (120) |
| Other assets | | 149 |
| Accounts payable and accrued expenses | 449 | (1,195) |
| Deferred revenue | (3,333) | (20,480) |
| Net cash used in operating activities | (8,472) | (11,443) |
| | | |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (38) | (40) |
| Proceeds from sale of investments available for sale | 7,985 | 11,555 |
| Purchases of investments available for sale | (33) | (5) |
| Net cash provided by investing activities | 7,914 | 11,510 |
| | | |
| **Cash flows from financing activities:** | | |
| Proceeds from the issuance of common stock, net | 6 | 1 |
| Net cash provided by financing activities | 6 | 1 |
| | | |
| Net (decrease) increase in cash | (552) | 68 |
| Cash at beginning of period | 1,661 | 1,442 |
| | | |
| Cash at end of period | $ 1,109 | $ 1,510 |

The accompanying notes are an integral part of these condensed financial statements.

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**SIX MONTHS ENDED JUNE 30, 2012 AND 2011**

## 1. Nature of Business

Osiris Therapeutics, Inc. ( we, us, our, or the Company ) is a Maryland corporation headquartered in Columbia, Maryland. We began operations on December 23, 1992 and were a Delaware corporation until, with approval of our stockholders, we reincorporated as a Maryland corporation on May 31, 2010. We are a leading stem cell company focused on developing and marketing products to treat serious medical conditions in the inflammatory and cardiovascular disease areas, and wound healing. Our biologic drug candidates utilize adult human mesenchymal stem cells, or MSCs, which can selectively differentiate, based on the tissue environment, into various tissue lineages, such as muscle, bone, cartilage, marrow stroma, tendon or fat. In addition, MSCs have anti-inflammatory properties and can prevent fibrosis or scarring, which gives MSCs the potential to treat a wide variety of medical conditions. Historically, our operations have consisted primarily of research, development and clinical activities under several research collaboration agreements to bring our biologic drug candidates to the marketplace. During the second quarter of 2012, we received authorization from Health Canada to market our stem cell therapy Prochymal® (remestemcel-L), for the treatment of acute graft-vs-host disease (GvHD) in children. This was the first marketing approval for one of our biologic drug candidates, and marks the world s first regulatory approval of a manufactured stem cell therapeutic product and the first therapy approved for GvHD. Subsequent to the approval by Health Canada, we have also been granted marketing consent for Prochymal for the same indication in New Zealand. We expect to commence commercial distribution during the second half of 2012.

During 2009, we created a Biosurgery business, which we began operating as a segment separate from our Therapeutics segment. Our Therapeutics segment is focused on developing and marketing products to treat medical conditions in the inflammatory and cardiovascular disease areas; and our Biosurgery segment focuses on products for wound healing and use in surgical procedures by harnessing the ability of cells and novel constructs to promote the body s natural healing.

## 2. Significant Accounting Policies

***Unaudited Interim Financial Statements***

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ( US GAAP ) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete financial statements. In the opinion of management, these statements include all adjustments (consisting of normal recurring adjustments) considered necessary to present a fair statement of our results of operations, financial position and cash flows. Operating results for any interim period are not necessarily indicative of the results that may be expected for the full year. This Quarterly Report on Form 10-Q should be read in conjunction with our financial statements and footnotes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

***Use of Estimates***

The preparation of financial statements in conformity with US GAAP requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Due to the inherent uncertainty involved in making those assumptions, actual results could differ from those estimates. We believe that the most significant estimates that affect our financial statements are those that relate to revenue recognition associated with our collaborative agreements, deferred tax assets, inventory valuation, and share-based compensation.

***Revenue Recognition***

To date, our Therapeutics segment has generated revenues from collaborative agreements and research licenses. We evaluate revenues from agreements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting. To recognize a delivered item in a multiple element arrangement, the delivered items must have value on a standalone basis and the delivery or performance must be probable and within our control for any delivered items that have a right of return. The determination of whether multiple elements of a collaboration agreement meet the criteria for separate units of accounting requires us to exercise judgment.

Revenues from research licenses are recognized as earned upon either the incurring of reimbursable expenses directly related to the particular research plan or the completion of certain development milestones as defined within the terms of the agreement. Payments received in advance of research performance are designated as deferred revenue. Non-refundable upfront license fees and certain other related fees are recognized on a straight-line basis over the development periods of the contract deliverables. Fees associated with substantive at risk performance based milestones are recognized as revenue upon their completion, as defined in the respective agreements. Incidental assignment of technology rights is recognized as revenue as it is earned and received.

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED FINANCIAL STATEMENTS (CONTINUED)**

**SIX MONTHS ENDED JUNE 30, 2012 AND 2011**

In October 2008, we entered into a Collaboration Agreement with Genzyme Corporation, then an independent and now a Sanofi company ( Genzyme ), for the development and commercialization of our biologic drug candidates, Prochymal and Chondrogen®. Under this agreement, Genzyme made non-contingent, non-refundable cash payments to us, totaling $130.0 million. The agreement provided Genzyme with certain rights to intellectual property developed by us, and required that we continue to perform certain development work related to the subject biologic drug candidates. As discussed in Note 15, Subsequent Events in our Annual Report on Form 10-K for the Year Ended December 31, 2011 ( 2011 10-K ), in February 2012, Sanofi issued a press release which included an update on their R&D pipeline, stating that it has discontinued its project with Prochymal for GvHD. The statement issued by Sanofi was made without consultation with or knowledge by us. Through our legal counsel, we have advised Sanofi that we are treating these public statements as Sanofi s election to terminate the collaboration agreement. The agreement provides for voluntary termination by Sanofi and that, upon such voluntary termination, all rights to Prochymal revert back to us, and we are free to commercialize or enter into commercialization agreements for Prochymal with other parties without restriction. While we have been proceeding on the basis that Sanofi has terminated the collaboration agreement, Sanofi has since advised us that it disagrees with our characterization of their press release. We have requested an explanation from Sanofi with respect to their statements regarding Prochymal. There can be no assurances as to the outcome of these matters. However, we continue to proceed with our Prochymal regulatory approval efforts and, if successful, commercialization, alone or with another collaborator.

We evaluated the deliverables related to the upfront payments made to us under the Genzyme collaboration agreement, and concluded that the various deliverables represent a single unit of accounting. For this reason, we deferred the recognition of revenue related to the upfront payments, and amortized these amounts to revenue on a straight-line basis over the estimated delivery period of the required development services, which extended through January 2012.

We recognized $3.3 million of revenue from this agreement during 2012, all of which came during the first fiscal quarter corresponding with the estimated end point date in January of 2012, compared to $10.0 million of revenue in each of the first two quarters of 2011. As of January 31, 2012, the upfront payments received under this contract had been fully amortized to revenue.

In October 2007, we entered into a collaborative agreement with the Juvenile Diabetes Research Foundation ( JDRF ) to conduct a Phase 2 clinical trial evaluating Prochymal as a treatment for type 1 diabetes mellitus. This collaborative agreement provides for JDRF to provide up to $4.0 million of contingent milestone funding to support the development of Prochymal for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus. The contingent milestone payments under the agreement are amortized to revenue on a straight line basis over the duration of our obligations under the collaborative agreement as they are received and earned. We have received all $4.0 million of the contingent milestones, and amortized the funding received over the duration of our obligations. We completed our work under this contract in fiscal 2011. As a result, we recognized approximately $200,000 of revenue in each of the first two fiscal quarters of 2011, and did not recognize any revenue under this agreement during fiscal 2012.

Our Therapeutics segment also earns royalty revenues and cost reimbursement under our adult expanded access program. Royalties are earned on the sale of human mesenchymal stem cells sold for research purposes. We recognize this revenue as sales are made. We recognized approximately $70,000 and $178,000, respectively, of royalty revenue for the three and six months ended June 30, 2012, compared to $23,000 and $63,000, respectively, in the comparable periods of 2011. During the six months ended June 30, 2012 and 2011, we received $23,000 and $75,000, respectively, in cost reimbursement for Prochymal used in our adult expanded access program.

As discussed in Note 4- *Segment Reporting* below, we also operate a Biosurgery segment, focused on developing high-end biologic products for use in wound healing and surgical procedures. We launched commercial distribution of our Biosurgery products in late 2010, and continued to increases our distribution volume throughout fiscal 2011. Due to the conditions required to preserve these products, customers may elect to have the product shipped to them, or we offer the customers use of our specially designed freezers for for storage for a maximum period of 30 days. We do not allow customers to store product at our facility for longer than 30 days. Legal title passes to the customers when the product either leaves our shipping dock, if the customer has elected to have the product shipped to them, or when it is placed by us in a specifically designated storage unit located at our facility under the terms discussed above, if they have elected to have us temporarily store the product for them. Due to the nature of the products and the manufacturing process, we do not allow refunds or returns.

We recognized revenues of approximately $1.6 million and $2.8 million during the three and six months ended June 30, 2012 compared to approximately $130,000 and $167,000 from the distribution of such products during the three and six months ended June 30, 2011.

***Research and Development Costs***

We expense internal and external research and development ( R&D ) costs, including costs of funded R&D arrangements and the manufacture of clinical batches of our biologic drug candidates used in clinical trials, in the period incurred.

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED FINANCIAL STATEMENTS (CONTINUED)**

**SIX MONTHS ENDED JUNE 30, 2012 AND 2011**

Beginning with the creation of our Biosurgery segment, we began to separately track research and development costs by segment. Total research and development costs for each of our operating segments are as follows:

| | Three Months Ended June 30, 2012 ($000s) | | | Three Months Ended June 30, 2011 ($000s) | | |
|---|---|---|---|---|---|---|
| | Therapeutics | Biosurgery | Total | Therapeutics | Biosurgery | Total |
| Research and development costs | $ 2,869 | $ 1,203 | $ 4,072 | $ 4,264 | $ 945 | $ 5,209 |

| | Six Months Ended June 30, 2012 ($000s) | | | Six Months Ended June 30, 2011 ($000s) | | |
|---|---|---|---|---|---|---|
| | Therapeutics | Biosurgery | Total | Therapeutics | Biosurgery | Total |
| Research and development costs | $ 5,616 | $ 2,419 | $ 8,035 | $ 8,109 | $ 1,811 | $ 9,920 |

We do not track internal development costs by project within the Therapeutics segment. We do, however, track external research and development costs by project, which were as follows:

| External R&D Costs By Indication | Three Months Ended June 30, 2012 ($000s) | 2011 ($000s) | Six Months Ended June 30, 2012 ($000s) | 2011 ($000s) |
|---|---|---|---|---|
| Acute myocardial infarction | $ 594 | $ 1,730 | $ 1,445 | $ 3,108 |
| Treatment-resistant GvHD | 142 | 139 | 242 | 293 |
| Refractory Crohn s disease | 157 | 478 | 373 | 881 |
| Other therapeutic programs | 276 | (155) | 431 | 87 |
| **Therapeutics external R&D costs -** | **1,169** | **2,192** | **2,491** | **4,369** |
| **Biosurgery external R&D costs -** | **1,368** | **315** | **1,926** | **498** |
| **Total External R&D Costs -** | **$ 2,537** | **$ 2,507** | **$ 4,417** | **$ 4,867** |

***Income (Loss) per Common Share***

Basic income (loss) per common share is calculated by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted income (loss) per common share adjusts basic income (loss) per share for the potentially dilutive effects of common share equivalents, using the treasury stock method, and includes the incremental effect of shares that would be issued upon the assumed exercise of stock options and warrants.

Diluted loss per common share for the three and six months ended June 30, 2012 excludes the 1,000,000 shares issuable upon the exercise of an outstanding out-of the money warrant, and all 1,913,072 of our outstanding options as of June 30, 2012, as their impact on our net loss is anti-dilutive. As a result, basic and diluted weighted average common shares outstanding are identical for these periods.

Diluted income per common share for the three and six months ended June 31, 2011 excludes the 1,000,000 shares issuable upon the exercise of an outstanding out-of the money warrant, and approximately 1,162,000 and 1,088,000, respectively, shares issuable upon the exercise of out-of the money stock options, as their effect is anti-dilutive.

A reconciliation of basic to diluted weighted average common shares outstanding for the applicable periods is as follows:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2012 (000s)** | **2011 (000s)** | **2012 (000s)** | **2011 (000s)** |
| Basic weighted average common shares outstanding | 32,860 | 32,821 | 32,845 | 32,814 |
| Dilutive weighted average options outstanding | | 313 | | 310 |
| Dilutive weighted average warrants outstanding | | | | |
| Diluted weighted average common shares outstanding | 32,860 | 33,134 | 32,845 | 33,124 |

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED FINANCIAL STATEMENTS (CONTINUED)**

**SIX MONTHS ENDED JUNE 30, 2012 AND 2011**

***Investments Available for Sale and Other Comprehensive Income (Loss)***

Investments available for sale consist primarily of marketable securities with maturities less than one year. Investments available for sale are valued at their fair value, with unrealized gains and losses reported as a separate component of stockholders equity in accumulated other comprehensive income. All realized gains and losses on our investments available for sale are recognized in results of operations as other income.

Investments available for sale are evaluated periodically to determine whether a decline in their value is other than temporary. The term other than temporary is not intended to indicate a permanent decline in value. Rather, it means that the prospects for near term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. We review criteria such as the magnitude and duration of the decline, as well as the reasons for the decline, to predict whether the loss in value is other than temporary. If a decline in value is determined to be other than temporary, the carrying value of the security is reduced and a corresponding charge to earnings is recognized.

***Inventory***

We began carrying inventory of our Biosurgery products on our balance sheet following commercial launch of such products. Inventory consists of raw materials, biologic products in process, and products available for distribution. We determine our inventory values using the first-in, first-out method. Inventory is valued at the lower of cost or market, and excludes units that we anticipate distributing for clinical evaluation.

Our Biosurgery inventory consists of the following as of June 30, 2012 and December 31, 2011:

| | June 30, 2012 ($000) | December 31, 2011 ($000) |
|---|---|---|
| Inventory | | |
| Raw materials and supplies | $ 139 | $ 184 |
| Finished goods | 336 | 583 |
| Total Biosurgery inventory | $ 475 | $ 767 |

We do not currently carry any inventory for our Therapeutics products, as we have yet to launch Prochymal for commercial distribution following its approval during the second quarter of 2012. Historically, the Therapeutics segment s operations have focused on clinical trials and

discovery efforts, and accordingly, manufactured clinical doses of our drug candidates were expensed as incurred, consistent with our accounting for all other research and development costs. Once we begin commercial distribution, all new Prochymal manufactured will be analyzed to differentiate between doses for commercial distribution, which would be carried as inventory, and those for future research and development efforts, which will continue to be expensed as incurred

***Share-Based Compensation***

We account for share-based payments using the fair value method.

We recognize all share-based payments to employees in our financial statements based on their grant date fair values, calculated using the Black-Scholes option pricing model. Compensation expense related to share-based awards is recognized on a straight-line basis for each vesting tranche based on the value of share awards that are expected to vest on the grant date, which is revised if actual forfeitures differ materially from original expectations. Awards of shares of our common stock to non-employee directors are valued at the closing price on the grant date.

A summary of option activity under both of our stock-based compensation plans for the six months ended June 30, 2012 is presented below.

| | Number of Shares | Weighted Average Exercise Price Per Share | Weighted Average Remaining Term (in Years) | Aggregate Intrinsic Value $(000) |
|---|---|---|---|---|
| Outstanding at January 1, 2012 | 1,702,072 | $ 9.06 | 6.8 | $ 1,533 |
| Granted at fair value | 271,000 | 5.08 | | |
| Exercised | (15,500) | 0.40 | | 75 |
| Forfeited | (44,500) | 9.68 | | |
| Outstanding at June 30, 2012 | 1,913,072 | 8.55 | 6.8 | 7,772 |
| | | | | |
| Exercisable at June 30, 2012 | 1,107,072 | 9.70 | 5.3 | 4,227 |

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED FINANCIAL STATEMENTS (CONTINUED)**

**SIX MONTHS ENDED JUNE 30, 2012 AND 2011**

The weighted average grant date fair value of options granted during the six months ended June 30, 2012 was $2.60 per share. We received approximately $6,000 in cash from the exercise of options during the six months ended June 30, 2012.

As of June 30, 2012, approximately 470,000 shares of common stock remain available for future share awards under our Amended and Restated 2006 Omnibus Plan.

Share-based compensation expense (including director compensation) included in our statements of operations for the three and six months ended June 30, 2012 and 2011 is allocable to our research and development and general and administrative activities as follows:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2012 ($000) | 2011 ($000) | 2012 ($000) | 2011 ($000) |
| Research and development | $ 185 | $ 221 | $ 322 | $ 474 |
| General and administrative | 117 | 169 | 365 | 520 |
| Total | $ 302 | $ 390 | $ 687 | $ 994 |

As of June 30, 2012, there was approximately $1.4 million of total unrecognized share-based compensation cost related to options granted under our plans, which will be recognized over a weighted-average period of less than one year, as the options vest.

**3. Collaboration Agreements**

We are a party to several material collaborative agreements and other contracts as fully described in Note 2 of our 2011 10-K. There have not been any material amendments to the terms of any of these agreements during 2012 that require disclosure. The accounting policies related to each of these contracts, including material impact on our financial statements, is included above under the Revenue Recognition section of Note 2*, Significant Accounting Policies*.

**4. Segment Reporting**

We manage our business in two reportable operating segments: the Therapeutics segment and the Biosurgery segment. Our Therapeutics segment focuses on developing and marketing products to treat medical conditions in the inflammatory and cardiovascular disease areas. Its operations have focused on clinical trials and discovery efforts to identify additional medical indications. Revenues for our Therapeutics segment have historically consisted primarily of collaborative research agreements and royalties as described in our 2011 10-K in the Revenue Recognition section of Note 2*, Significant Accounting Policies.* As discussed above under Note 1*, Nature of Business,* during the second quarter of 2012, we received authorization to market our stem cell therapy Prochymal in both Canada and New Zealand. We expect to begin commercial distribution of Prochymal in the second half of 2012.

Our Biosurgery segment is focused on the development, manufacture and distribution of biologic products for wound healing and use in surgical procedures by harnessing the ability of cells and novel constructs to promote the body s natural healing.

Substantially all of our revenues and assets are attributed to and are received from entities located in the United States.

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED FINANCIAL STATEMENTS (CONTINUED)**

**SIX MONTHS ENDED JUNE 30, 2012 AND 2011**

The costs specifically attributable to each of our segments for the three and six months ended June 30, 2012 and 2011 are as follows:

| | Three Months Ended June 30, 2012 ($000s) | | | Three Months Ended June 30, 2011 ($000s) | | |
|---|---|---|---|---|---|---|
| | Therapeutics | Biosurgery | Total | Therapeutics | Biosurgery | Total |
| **Product revenues** | $ | $ 1,626 | $ 1,626 | $ | $ 130 | $ 130 |
| Cost of product revenues | | 552 | 552 | | 55 | 55 |
| Gross profit | | 1,074 | 1,074 | | 75 | 75 |
| **Revenue from collaborative research agreements and royalties** | 98 | | 98 | 10,224 | | 10,224 |
| Operating expenses: | | | | | | |
| Research and development | 2,869 | 1,203 | 4,072 | 4,264 | 945 | 5,209 |
| General and administrative | 1,037 | 381 | 1,418 | 3,038 | 242 | 3,280 |
| | 3,906 | 1,584 | 5,490 | 7,302 | 1,187 | 8,489 |
| (Loss) income from operations | $ (3,808) | $ (510) | $ (4,318) | $ 2,922 | $ (1,112) | $ 1,810 |

| | Six Months Ended Ended June 30, 2012 ($000s) | | | Six Months Ended June 30, 2011 ($000s) | | |
|---|---|---|---|---|---|---|
| | Therapeutics | Biosurgery | Total | Therapeutics | Biosurgery | Total |
| **Product revenues** | $ | $ 2,763 | $ 2,763 | $ | $ 167 | $ 167 |
| Cost of product revenues | | 939 | 939 | | 70 | 70 |
| Gross profit | | 1,824 | 1,824 | | 97 | 97 |
| **Revenue from collaborative research agreements and royalties** | 3,544 | | 3,544 | 20,619 | | 20,619 |
| Operating expenses: | | | | | | |
| Research and development | 5,616 | 2,419 | 8,035 | 8,109 | 1,811 | 9,920 |
| General and administrative expenses and fees | 2,188 | 753 | 2,941 | 4,537 | 439 | 4,976 |
| | 7,804 | 3,172 | 10,976 | 12,646 | 2,250 | 14,896 |
| (Loss) income from operations | $ (4,260) | $ (1,348) | $ (5,608) | $ 7,973 | $ (2,153) | $ 5,820 |

In general, our total assets, including long-lived assets such as property and equipment, and our capital expenditures are not specifically allocated to any particular operating segment. Accordingly, capital expenditures and total asset information by reportable segment is not presented. The only assets that are allocated to the individual segments are the inventory and accounts receivable specifically related to each segment.

The assets specifically attributable to each of our segments as of June 30, 2012 and December 31, 2011 are as follows:

| | June 30, 2012 ($000s) | | | December 31, 2011 ($000s) | | |
|---|---|---|---|---|---|---|
| | Therapeutics | Biosurgery | Total | Therapeutics | Biosurgery | Total |
| **Segment assets:** | | | | | | |
| Accounts Receivable | $ 117 | $ 1,276 | $ 1,393 | $ 37 | $ 691 | $ 728 |
| Inventory | | 475 | 475 | | 767 | 767 |
| Total segment assets | $ 117 | $ 1,751 | $ 1,868 | $ 37 | $ 1,458 | $ 1,495 |

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED FINANCIAL STATEMENTS (CONTINUED)**

**SIX MONTHS ENDED JUNE 30, 2012 AND 2011**

## 5. Income Taxes

We calculate our interim tax provision in accordance with the guidance for accounting for income taxes in interim periods. At the end of each interim period, we estimate the annual effective tax rate and apply that tax rate to our ordinary quarterly pre-tax income. The tax expense or benefit related to significant, unusual or extraordinary discrete events during the interim period is recognized in the interim period in which those events occurred. In addition, the effect of changes in enacted tax laws or rates or tax status is recognized in the interim period in which the change occurs.

For income tax reporting purposes, we anticipate a loss for the year ending December 31, 2012. The primary difference for 2012 between our net loss for financial reporting purposes and the loss for income tax reporting purposes relates to the recognition of deferred revenue from our collaborative agreement with Genzyme, which was previously reported for income tax purposes. During the three months ended June 30, 2012, we filed our federal and state income tax returns for the fiscal year ended December 31, 2011 and trued-up our income tax receivable to the short-term deferred tax asset that was on our December 2011 balance sheet by recognizing a tax benefit of $32,000. Upon filing these 2011 tax returns, we reclassified the short-term deferred tax asset of $2.2 million to income tax receivable, which is a component of Prepaid expenses and other current assets in our unaudited June 30, 2012 balance sheet. Similarly, during the three months ended June 30, 2011, we filed our fiscal 2010 income tax returns and recognized income tax expense of $43,000 when truing up our short-term deferred tax asset to the amounts reported in our fiscal 2010 income tax returns.

At June 30, 2012, the balance of our net operating loss and tax credit carryforwards was approximately $100.3 million. Our deferred tax assets have been fully reserved in both 2012 and 2011 since their ultimate future realization cannot be assured.

## 6. Investments Available for Sale

Investments available for sale consisted of the following as of June 30, 2012 and December 31, 2011:

| | June 30, 2012 $000 | | | | December 31, 2011 $000 | | | |
|---|---|---|---|---|---|---|---|---|
| | Cost | Unrealized Gain | Unrealized Loss | Fair Value | Cost | Unrealized Gain | Unrealized Loss | Fair Value |
| **Cash equivalents:** | | | | | | | | |
| Money market funds & | $ 1,521 | $ | $ | $ 1,521 | $ 527 | $ | $ | $ 527 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| certificates of deposit | | | | | | | | |
| Commercial paper | 15,393 | 3 | (2) | 15,394 | 15,411 | 4 | (1) | 15,414 |
| | 16,914 | 3 | (2) | 16,915 | 15,937 | 4 | (1) | 15,940 |
| **Short term investments:** | | | | | | | | |
| Municipal securities | | | | | 1,612 | | (1) | 1,611 |
| Corporate notes and bonds | 20,518 | 7 | (4) | 20,521 | 26,834 | 16 | | 26,850 |
| US & International government agencies | 200 | 1 | | 201 | 1,201 | 2 | | 1,203 |
| | 20,718 | 8 | (4) | 20,722 | 29,647 | 18 | (1) | 29,664 |
| **Investments available for sale** | **$ 37,632** | **$ 11** | **$ (6)** | **$ 37,637** | **$ 45,584** | **$ 22** | **$ (2)** | **$ 45,604** |

The following table summarizes maturities of our investments available for sale as of June 30, 2012 and December 31, 2011:

| | June 30, 2012 $000 | | December 31, 2011 $000 | |
|---|---|---|---|---|
| | Cost | Fair Value | Cost | Fair Value |
| **Maturities:** | | | | |
| **Within 3-months** | **$ 12,254** | **$ 12,256** | **$ 42,612** | **$ 42,627** |
| **Between 3 12 months** | **17,886** | **17,886** | | |
| **Between 1 2 years** | **7,492** | **7,495** | **2,972** | **2,977** |
| **Investments available for sale** | **$ 37,632** | **$ 37,637** | **$ 45,584** | **$ 45,604** |

Realized gains and investment income earned on investments available for sale were $21,000 and $39,000, respectively, for the three and six months ended June 30, 2012, and have been included as a component of Other income, net in the accompanying financial statements.

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED FINANCIAL STATEMENTS (CONTINUED)**

**SIX MONTHS ENDED JUNE 30, 2012 AND 2011**

## 7. Fair Value

Fair value is defined as the price at which an asset could be exchanged or a liability transferred (an exit price) in an orderly transaction between knowledgeable, willing parties in the principal or most advantageous market for the asset or liability. Where available, fair value is based on observable market prices or parameters or derived from such prices or parameters. Where observable prices or inputs are not available, valuation models are applied.

Financial assets recorded at fair value in the accompanying financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. The levels are directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities, and are as follows:

*Level 1* Inputs are unadjusted, quoted prices in active markets for identical assets at the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The fair valued assets we hold that are generally included in this category are money market securities where fair value is based on publicly quoted prices.

*Level 2* Inputs are other than quoted prices included in Level 1, which are either directly or indirectly observable for the asset or liability through correlation with market data at the reporting date and for the duration of the instrument s anticipated life.

The fair valued assets we hold that are generally included in this category are investment grade short-term securities.

*Level 3* Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities and which reflect management s best estimate of what market participants would use in pricing the asset or liability at the reporting date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

When quoted prices in active markets for identical assets are available, we use these quoted market prices to determine the fair value of financial assets and classify these assets as Level 1. In other cases where a quoted market price for identical assets in an active market is either not available or not observable, we obtain the fair value from a third party vendor that uses pricing models, such as matrix pricing, to determine fair value. These financial assets would then be classified as Level 2. In the event quoted market prices were not available, we would determine fair value using broker quotes or an internal analysis of each investment s financial statements and cash flow projections. In these instances, financial assets would be classified based upon the lowest level of input that is significant to the valuation. Thus, financial assets might be classified in Level 3 even though there could be some significant inputs that may be readily available. To date, we have never had any assets that were required to be classified as Level 3.

Assets and liabilities measured at fair value on a recurring basis are summarized below as of June 30, 2012 and December 31, 2011:

| | June 30, 2012 ($000s) | | | |
|---|---|---|---|---|
| | Level I | Level II | Level III | Total |
| **Assets** | | | | |
| Cash equivalents | $ 1,521 | $ | $ | $ 1,521 |
| Government obligations | 201 | | | 201 |
| Agency obligations | | 20,521 | | 20,521 |
| Corporate debt securities & commercial paper | | 15,394 | | 15,394 |
| **Investments available for sale** | **$ 1,722** | **$ 35,915** | **$** | **$ 37,637** |

| | December 31, 2011 ($000s) | | | |
|---|---|---|---|---|
| | Level I | Level II | Level III | Total |
| **Assets** | | | | |
| Cash equivalents | $ 27 | $ | $ | $ 27 |
| Government obligations | 1,203 | | | 1,203 |
| Certificates of deposit | | 500 | | 500 |
| Agency obligations | | 26,850 | | 26,850 |
| Corporate debt securities & commercial paper | | 15,413 | | 15,413 |
| Municipal securities | | 1,611 | | 1,611 |
| **Investments available for sale** | **$ 1,230** | **$ 44,374** | **$** | **$ 45,604** |

## 8. Subsequent Events

We evaluated our June 30, 2012 financial statements for subsequent events through the date the financial statements were issued. We are not aware of any subsequent events which would require recognition or disclosure in the financial statements.

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## Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

### CAUTIONARY STATEMENTS ABOUT FORWARD-LOOKING INFORMATION

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Statements included or incorporated herein which are not historical facts are forward looking statements. When used in this Quarterly Report, the words *estimates, expects, anticipates, projects, plans, intends, believes, forecasts* and variations of such words or similar expressions are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying forward looking statements.

Forward looking statements reflect management s current views with respect to future events and performance and are based on currently available information and management s assumptions regarding future events. While management believes that its assumptions are reasonable, forward-looking statements are subject to various known and unknown risks and uncertainties and actual results may differ materially from those expressed or implied herein. In connection with the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, the Company notes that certain factors, among others, which could cause future results to differ materially from the forward-looking statements, expectations and assumptions expressed or implied herein are discussed in greater detail in our Annual Report on Form 10-K under Part I Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 1A Risk Factors, and may be discussed elsewhere herein or in other documents we file with the Securities and Exchange Commission, or SEC. Examples of forward-looking statements may include, without limitation, statements regarding any of the following: our product development efforts; our clinical trials and anticipated regulatory requirements, and our ability to successfully navigate these requirements; the success of our product candidates in development; status of the regulatory process for our biologic drug candidates; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and clinical and commercialization strategy for mesenchymal stem cells (MSCs) and biologic drug candidates and marketed biosurgery products (including Prochymal® , Chondrogen® , Grafix® and Ovation® ); our cash needs; patents, trademarks and other proprietary rights; the safety and ability of our products and potential products to treat disease; our ability to supply a sufficient amount of our marketed products or product candidates and, if or insofar as approved or otherwise commercially available, products to meet demand; our costs to comply with governmental regulations; our relationship (current and future) with collaborating partners; our ability to maintain and benefit from, or exit from our collaborative arrangements; our ability to benefit from government contracts; our plans for or success of sales and marketing; our plans regarding facilities; our ability to establishing and maintain reimbursement for our commercially available products; types of regulatory frameworks we expect will be applicable to our products and potential products; and results of our scientific research.

Readers are cautioned that all forward-looking statements attributable to us or persons acting on our behalf apply only as of the date of this Quarterly Report and are expressly qualified in their entirety by the cautionary statements included herein. We undertake no obligation to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances and do not intend to do so.

You should read the following management s discussion and analysis of our financial condition and results of operations in conjunction with our audited Financial Statements and related notes thereto and other disclosures included as part of our Annual Report on Form 10-K for the year ended December 31, 2011, and our unaudited Condensed Financial Statements for the three and six month periods ended June 30, 2012 and other disclosures included in this Quarterly Report on Form 10-Q and our Quarterly Report on Form 10-Q for the first fiscal quarter of 2012. Our Condensed Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States, and are presented in U.S. dollars.

There are a number of risks and uncertainties that could cause our actual results to differ materially from the forward-looking statements contained in this report. Some of the important factors that could cause our actual results to differ materially from the forward-looking statements we make in this report are set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 under Part I Item 1A Risk Factors. There may be other factors that may cause our actual results to differ materially from the forward-looking statements.

When we use the terms Osiris, we, us, and our we mean Osiris Therapeutics, Inc., a Maryland corporation.

**Introduction and Overview**

The following is a discussion and analysis of our financial condition and results of operations for the three and six month periods ended June 30, 2012 and 2011. You should read this discussion together with the accompanying unaudited condensed financial statements and notes and with our Annual Report on Form 10-K for the year ended December 31, 2011. Historical results and any discussion of prospective results may not indicate our future performance. See Cautionary Statements About Forward-Looking Information.

We are a leading stem cell company headquartered in Columbia, Maryland and focused on developing and marketing products to treat medical conditions in the inflammatory, cardiovascular, orthopedic and wound healing markets. We have two business segments, Therapeutics and Biosurgery. Our Therapeutics business is focused on developing biologic stem cell drug candidates from a readily available and non-controversial source adult bone marrow. Our Biosurgery business, created in 2009 and operating as a separate segment since 2010, works to harness the ability of cells and novel constructs to promote the body s natural healing with the goals of improving surgical outcomes and offering better treatment options for patients and physicians.

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In our Biosurgery business, we currently manufacture, market and distribute Grafix and Ovation for tissue repair. In our Therapeutics segment, our pipeline of internally developed biologic drug candidates under evaluation includes Prochymal for inflammatory, autoimmune and cardiovascular indications, as well as Chondrogen for arthritis in the knee. We believe our stem cell therapeutic products have significant therapeutic potential because of their ability to regulate inflammation, promote tissue regeneration and prevent pathological scar formation.

We began operations on December 23, 1992 and were a Delaware corporation until, with approval of our stockholders, we reincorporated as a Maryland corporation on May 31, 2010.

***Therapeutics Segment.*** Our Therapeutics segment is focused on developing biologic stem cell drug candidates from a readily available and non-controversial source adult bone marrow. Our lead biologic drug candidate, Prochymal (remestemcel-L) has now been approved for the treatment of refractory acute graft versus host disease ( GvHD ) in pediatric patients. We have an Expanded Access Program for pediatric and adult patients in eight countries, including the U.S. Prochymal is also being evaluated in clinical trials for Crohn s disease, acute myocardial infarction, type 1 diabetes and gastrointestinal injury resulting from radiation exposure (animal rule). Our pipeline of internally developed biologic drug candidates also includes Chondrogen for osteoarthritis in the knee.

The following table summarizes the status of our biologic drug candidates.

| Drug Candidate | Indication | Status |
|---|---|---|
| **Prochymal** | Pediatric Refractory Acute GvHD | Marketing Approval received from Health Canada in May 2012 and from Medsafe (New Zealand s medical regulatory agency) in June 2012 |
| | Refractory Acute GvHD in pediatric and adult patients | Available in eight countries under Expanded Access Programs |
| | Biologics Refractory Crohn s Disease | Phase 3 |
| | Acute Myocardial Infarction | Phase 2 |
| | Type I Diabetes Mellitus | Phase 2 |
| | Acute Radiation Syndrome | Phase 3(Animal Rule) |
| **Chondrogen** | Osteoarthritis & Cartilage Protection | Phase 2 |

**Clinical Program Update**

In May 2012, we received approval from Health Canada to market Prochymal (remestemcel-L), for the treatment of refractory acute GvHD in children. We believe this is the world s first regulatory approval of a stem cell therapeutic drug product and the first therapy approved specifically for GvHD, a devastating complication of bone marrow transplantation that kills up to 80 percent of children affected, many within just weeks of diagnosis.

Prochymal was approved under Health Canada s Notice of Compliance with conditions (NOC/c) Policy, which provides expedited market clearance to high quality medical products that address significant unmet medical conditions and which have demonstrated favorable risk/benefit profile in clinical trials. Under the NOC/c pathway, the sponsor must agree to carry out confirmatory clinical testing.

Health Canada s approval was made following the recommendation of an independent expert advisory panel commissioned to evaluate the Prochymal s safety and efficacy. In support of the application, Osiris submitted over 90,000 pages of data generated over a 20 year development cycle. In Canada, Prochymal is now approved for the management of acute GvHD in children who fail to respond to steroids. The approval was based on the results from clinical studies evaluating Prochymal in patients with severe refractory acute GvHD. Prochymal demonstrated a clinically significant response 28 days post initiation of therapy in 61-64 percent of patients treated. Furthermore, treatment with Prochymal resulted in a statistically significant improvement in survival when compared to an historical control population of pediatric patients with refractory GvHD (p=0.028). The survival benefit was most pronounced in patients with the most severe forms of GvHD. As a condition of approval, the clinical benefit of Prochymal will be further evaluated in a case-matched confirmatory study.

In addition to the extensive patent protection for Prochymal, which includes 48 issued patents, Health Canada s decision will also provide Prochymal with regulatory exclusivity within the territory. Canada affords eight years of exclusivity to Innovative Drugs such as Prochymal, and an additional six-month pediatric extension is available since it is intended to treat a pediatric population.

There have not been any other significant changes to our clinical programs in our Therapeutics segment since we filed our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

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***Biosurgery Segment.*** Our Biosurgery segment seeks to harness the ability of cells and novel constructs to promote the body s natural healing, with the goals of improving surgical outcomes and offering better treatment options for patients and physicians. During the third quarter of 2010, we launched limited commercial distribution of several products developed and manufactured by our Biosurgery segment, including Grafix and Ovation. Disease targets for Biosurgery products commercialized or in development include diabetic foot ulcers, venous stasis ulcers, dermal burns, and various orthopedic conditions.

Grafix is a three-dimensional tissue matrix designed for application directly to acute and chronic wounds, including diabetic foot ulcers and burns. Flexible and conformable to complex anatomies, this cellular repair matrix provides a rich source of extracellular matrix, viable endogenous MSCs and epithelial cells, as well as growth factors directly to the site of the wound, protecting the area from inflammation, scarring and infection.

Ovation is a novel cellular repair matrix designed for use in surgical applications where bone tissue repair is needed. Easily applied to the site of injury, Ovation provides the three essential components of periosteum collagen matrix, viable endogenous MSCs and key growth factors such as BMPs and VEGF to enable tissue regeneration.

Grafix and Ovation are regulated by the FDA under 21CFR Part 1271, Human Cells, Tissues and Cellular and Tissue-based Products ( HCT/Ps ). We are registered with the FDA as a tissue establishment and are accredited by the American Association of Tissue Banks ( AATB ). Extensive donor screening, serological testing, bioburden testing and sterility testing is performed on every lot to demonstrate suitability for transplantation. Our Biosurgery products are all manufactured in our Columbia, Maryland facility. Each lot is tested to confirm viable cell content post thaw.

We market and distribute both Grafix and Ovation through a network of distributors as well as directly to hospitals and clinics. A significant market for Grafix is chronic wounds, which are primarily treated in the outpatient setting, and to obtain full reimbursement for use in the outpatient setting, a prospective randomized clinical trial comparing the standard of care to Grafix is needed.

We have received transitional pass-through status from the Center for Medicare & Medicaid Services ( CMS ), with C-Codes being designated for Grafix. Further, the product has been assigned pass-through status under Medicare s outpatient prospective payment system ( OPPS ), effective July 1, 2012. CMS also issued a preliminary positive decision for the assignment of permanent Healthcare Common Procedure Coding System (HCPCS) Q-codes for Grafix. If the decision is made permanent, it is anticipated that the Q-codes would be available starting in January 2013. The assignment of unique Q-codes will assist in facilitating reimbursement in the physician office setting, offering additional access for Medicare patients.

A study designed to allow for the collection of data necessary to obtain the permanent HCPCS Q-codes began during the second fiscal quarter of 2012.

We are a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. We have developed an extensive intellectual property portfolio to protect our technology including 48 U.S. and 153 foreign

patents owned or licensed. We have 38 U.S. patent applications pending and 96 foreign patent applications pending.

**Financial Operations Overview**

*Revenue*

In the fourth quarter of 2008, we entered into a collaboration agreement with Genzyme Corporation, then an independent and now a Sanofi company, for the development and commercialization of Prochymal and Chondrogen. Under the terms of the agreement, we retained the rights to commercialize Prochymal and Chondrogen in the United States and Canada, and Genzyme was granted exclusive rights to commercialize Prochymal and Chondrogen in all other countries, except with respect to GvHD in Japan, where Prochymal has previously been licensed to JCR Pharmaceuticals Co., Ltd. Under the agreement, we were paid $130.0 million for these rights. During the fiscal quarter ended March 31, 2012 we recognized revenue of $3.3 million, which was the final deferred revenue associated with the $130.0 million upfront payment. We recognized $10.0 million of revenue from the amortization of the upfront payment during each of the first two fiscal quarters of 2011.

The collaboration agreement provides that it will expire upon the completion of all development plans stipulated in the agreement and the expiration of all payment obligations; however, in addition to certain opt out rights, Genzyme may terminate the agreement early and without further obligation at any time, and either party may terminate the agreement due to non-performance, material breach or insolvency.

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In February 2012, Sanofi issued a press release which included an update on their R&D pipeline, stating that it has discontinued its project with Prochymal for GvHD. The statement issued by Sanofi was made without consultation with or knowledge by us. Through our legal counsel, we have advised Sanofi that we are treating these public statements as Sanofi s election to terminate the collaboration agreement. The agreement provides for voluntary termination by Sanofi and that, upon such voluntary termination, all rights to Prochymal revert back to us, and we are free to commercialize or enter into commercialization agreements for Prochymal with other parties without restriction. While we have been proceeding on the basis that Sanofi has terminated the collaboration agreement, Sanofi has since advised us that it disagrees with our characterization of their press release. We have requested an explanation from Sanofi with respect to their statements regarding Prochymal. There can be no assurances as to the outcome of these matters. However, we continue to proceed with our Prochymal regulatory approval efforts and, if successful, commercialization, alone or with another collaborator.

In prior years, we entered into strategic agreements with other companies for the development and commercialization of select stem cell biologic drug candidates for specific indications and geographic markets. In 2007, we entered into a collaborative agreement with the Juvenile Diabetes Research Foundation (JDRF) to conduct a Phase 2 clinical trial evaluating Prochymal as a treatment for type 1 diabetes mellitus. In 2003, we entered into an agreement with JCR Pharmaceuticals, granting it exclusive rights to Prochymal for the treatment of GvHD and other hematological malignancies in Japan. We did not recognize any revenue from these other agreements during fiscal 2012. We recognized approximately $240,000 of revenue from the JDRF collaboration during each of the first two fiscal quarters of 2011.

*Research and Development Costs*

Our research and development costs consist of expenses incurred in identifying, developing and testing biologic drug candidates and biologic tissue based products. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for independent monitoring and analysis of our clinical trials, costs of contract research and manufacturing, costs of facilities, and the costs of manufacturing clinical batches of biologic drug candidates, quality control supplies and material to expand biologic drug candidates.

Consistent with our focus on the development of biologic drug candidates with potential uses in multiple indications, many of our costs are not attributable to a specifically identified product. We use our employee and infrastructure resources across several projects. Accordingly, we do not account for internal research and development costs on a project-by-project basis. From inception in December 1992 through June 30, 2012, we incurred aggregate research and development costs of approximately $418 million.

During the three and six months ended June 30, 2012, we incurred $2.9 million and $5.6 million, respectively, of research and development costs in our Therapeutics segment and $1.2 million and $2.4 million in our Biosurgery segment. During the three and six months ended June 30, 2011, our total research and development costs were $4.3 million and $8.1 million, respectively, for our Therapeutics segment and $945,000 and $1.8 million for our Biosurgery segment

We expect our research and development expenses to continue to be substantial in the future, as we continue our clinical trial activity for our existing biologic drug candidates as they advance through the development cycle, and as we invest in additional product opportunities and research programs. Clinical trials and preclinical studies are time-consuming and expensive. Our expenditures on current and future preclinical and clinical development programs are subject to many uncertainties. We test our products in several preclinical studies, and we then conduct clinical trials for those biologic drug candidates that we determine to be the most promising. As we obtain results from clinical trials, we may elect to discontinue or delay trials for some biologic drug candidates in order to focus our resources on more promising biologic drug candidates. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, size of trial and intended use of a biologic drug candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a

variety of factors, including:

- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the length of time required to enroll trial participants;
- the duration of patient treatment and follow-up;
- the costs of producing supplies of the biologic drug candidates needed for clinical trials and regulatory submissions;
- the efficacy and safety profile of the biologic drug candidate; and
- the costs and timing of, and the ability to secure, regulatory approvals.

As a result of these uncertainties, we are unable to determine with any significant degree of certainty the duration and completion costs of our research and development projects or when and to what extent we will generate revenues from the commercialization and sale of any of our biologic drug candidates.

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*General and Administrative Expenses*

General and administrative expenses consist primarily of the costs associated with our general management, including salaries, allocations of facilities and related costs, and professional fees such as legal and accounting expenses. We have experienced a general decrease in general and administrative costs as the result of our continued cost cutting efforts and the refinement of many of our general business processes, as well as a reduction in share-based compensation expense. However, we expect future expense increases to likely result from the hiring of additional operational, financial, accounting, facilities engineering and information systems personnel we approach the commercial launch of Prochymal for an initial indication.

*Other Income, Net*

Other income consists of interest earned on our cash and investments available for sale and realized gains and losses incurred on the sale of these investments. Interest expense consists of interest incurred on capital leases and other debt financings. We do not expect to incur material interest expense in the future as we had extinguished all of our outstanding debt prior to fiscal 2009.

*Provision for Income Taxes*

Until fiscal 2010, we have not recognized any net deferred tax assets or liabilities in our financial statements because we cannot assure their future realization. Because realization of deferred tax assets is dependent upon future earnings, a full valuation allowance has been recorded on the net deferred tax assets, which relate primarily to net operating loss and research and development carry-forwards. In the event that we become profitable within the next several years, we have net deferred tax assets (before a 100% valuation allowance) of approximately $100.3 million that may be utilized prior to us having to recognize any income tax expense or make payments to the taxing authorities other than the alternative minimum tax. The income from the upfront fees we received from Genzyme Corporation was required to be recognized over several years from 2008 through the first quarter 2012 for financial statement reporting purposes. For income tax purposes, the income was required to be fully recognized in 2009 and 2010. This resulted in our releasing $3.2 million of the valuation allowance on our net deferred tax assets in fiscal 2010. We recognized $1.0 million of the resulting deferred tax asset in 2011, and we recognized the remaining $2.2 million deferred tax asset in 2012. Upon filing these 2011 tax returns, we reclassified the short-term deferred tax asset to income tax receivable, which is a component of Prepaid expenses and other current assets in our unaudited June 30, 2012 balance sheet.

During the three months ended June 30, 2012, we filed our federal and state income tax returns for the fiscal year ended December 31, 2011 and trued-up our income tax receivable to the short-term deferred tax asset that was on our December 2011 balance sheet by recognizing a tax benefit of $32,000. Similarly, during the three months ended June 30, 2011, we filed our fiscal 2010 income tax returns and recognized income tax expense of $43,000 when truing up our short-term deferred tax asset to the amounts reported in our fiscal 2010 income tax returns.

**Critical Accounting Policies**

There have been no material changes in our critical accounting policies, estimates and judgments during the three andsix months ended June 30, 2012 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2011, other than as disclosed herein.

**Results of Operations**

***Comparison of Three Months Ended June 30, 2012 and 2011***

*Biosurgery Product Revenues*

During the three months ended June 30, 2012, we continued to expand our distribution efforts in our Biosurgery segment, both through in-house personnel as well as through our expanding distributor network. During the three months ended June 30, 2012, we recognized $1.6 million of product revenues from the distribution of Grafix and Ovation and realized gross profit of $1.1 million. Revenues from the distribution of Biosurgery products in the second fiscal quarter of 2011 were $130,000, and gross profit was $75,000. The increase in revenue and gross profit in 2012 is due to volume increases as we have continued to expand our distribution network. We are continuing to distribute a substantial amount of these products for clinical evaluation and expect commercial distribution to ramp up slowly until such time as we are able to build the commercial capabilities necessary to drive more widespread adoption. Until such time as we ramp up our Biosurgery manufacturing activities to fully utilize our manufacturing facilities, our costs to manufacture these products are likely to vary significantly.

*Revenues from Collaborative Research Agreements and Royalties*

Revenues from collaborative research agreements and royalties were $98,000 for the three months ended June 30, 2012, compared to $10.2 million for comparable fiscal period 2011. All of the deferred revenues from the Genzyme and JDRF agreements had been amortized prior to the second quarter of 2012, so revenues from collaborative research agreements and royalties during that period consist primarily of royalties and cost reimbursement under our adult expanded access program. Revenues for the three months ended June 30, 2011 consisted primarily of $10.0 million from the Genzyme agreement, with the remainder of the collaborative research revenues coming from the JDRF collaboration.

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*Research and Development Expenses*

Research and development expenses for the three months ended June 30, 2012 were $4.1 million as compared to research and development expenses of $5.2 million for the same period of 2011, as follows:

| | Three Months Ended June 30, | |
|---|---|---|
| | **2012 ($000)** | **2011 ($000)** |
| Therapeutics | $ 2,869 | $ 4,264 |
| Biosurgery | 1,203 | 945 |
| | $ 4,072 | $ 5,209 |

The decrease in research and development expenses in our Therapeutics segment in the second quarter of fiscal 2012 compared to the same period in fiscal 2011 reflects lower expenses in our acute myocardial infarction clinical trial, which was fully enrolled in the third quarter of 2011, resulting in lower patient and site costs since then. The increase in research and development expenses in our Biosurgery segment in fiscal 2012 reflects our increased process improvement efforts and development expenses incurred in exploring additional products to bring to market and the enrollment of the clinical trial required for to obtain cost reimbursement for Grafix.

*General and Administrative Expenses*

General and administrative expenses were $1.4 million for the three months ended June 30, 2012 compared to $3.3 million for the corresponding period in fiscal 2011. We incurred $381,000 of sales, general and administrative expenses related to our Biosurgery segment during the three months ended June 30, 2012, compared to $242,000 in the corresponding period of fiscal 2011. General and administrative expenses incurred in our Therapeutics segment during the second quarter of fiscal 2012 were $1.0 million, compared to $3.0 million in the corresponding period of fiscal 2011, which included $1.7 million of non-cash compensation expense related to the extension of the expiration of a Warrant held by the chairman of our board of directors. The remaining decrease is the result of our continued cost cutting efforts and the refinement of many of our general business processes.

*Other Income, Net*

Other income, net was $21,000 for the three months ended June 30, 2012, compared to $25,000 in the corresponding period in fiscal 2011. Our investments available for sale consist primarily of short-term, investment grade securities with a focus on avoiding market risk. We did not incur any interest expense during either 2012 or 2011.

*Benefit (Provision) for Income Taxes*

During the three months ended June 30, 2012, we filed our federal and state income tax returns for the fiscal year ended December 31, 2011 and trued-up our income tax receivable to the short-term deferred tax asset that was on our December 2011 balance sheet by recognizing a tax benefit of $32,000. Similarly, during the three months ended June 30, 2011, we filed our fiscal 2010 income tax returns and recognized income tax expense of $43,000 when truing up our short-term deferred tax asset to the amounts reported in our fiscal 2010 income tax returns.

*Other Comprehensive Income (Loss)*

Our other comprehensive income (loss) consists of the unrealized gain or loss on our investments available for sale when they are marked-to-market at the end of each reporting period. During the second quarter of fiscal 2012, we recognized an unrealized gain of $1,000 compared to unrealized gains of $22,000 during the same period of fiscal 2011.

***Comparison of Six Months Ended June 30, 2012 and 2011***

*Biosurgery Product Revenues*

During the six months ended June 30, 2012, we continued to expand our distribution efforts in our Biosurgery segment, both through in-house personnel as well as through our expanding distributor network. During this period, we recognized $2.8 million of product revenues from the distribution of our Biosurgery products and realized gross profit of $1.8 million. Revenues from the distribution of Biosurgery products in the comparable period of fiscal 2011 were $167,000, and gross profit was $97,000. The increase in revenue and gross profit in 2012is due to volume increases as we have continued to expand our distribution network. We are continuing to distribute a substantial amount of these products for clinical evaluation and expect commercial distribution to ramp up slowly until such time as we are able to build the commercial capabilities necessary to drive more widespread adoption. Until such time as we ramp up our Biosurgery manufacturing activities to fully utilize our manufacturing facilities, our costs to manufacture these products are likely to vary significantly.

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*Revenues from Collaborative Research Agreements and Royalties*

Revenues from collaborative research agreements and royalties were $3.5 million for the six months ended June 30, 2012, compared to $20.6 million for the comparable period of fiscal 2011. We recognized the final $3.3 million in revenue from our collaborative agreement with Genzyme during January 2012 and approximately $200,000 of royalty revenues and cost reimbursement under our adult expanded access program. All of the revenue from the JDRF collaboration had been recognized prior to 2012. Revenues for the six months ended June 30, 2011 consisted primarily of $20.0 million from the Genzyme agreement, $480,000 from the JDRF collaboration, and approximately $150,000 of royalty revenues and cost reimbursements from our expanded access program for adult acute Graft versus Host Disease.

*Research and Development Expenses*

Research and development expenses for the six months ended June 30, 2012 were $8.0 million as compared to research and development expenses of $9.9 million for the same period of 2011, as follows:

| | Six Months Ended June 30, | |
|---|---|---|
| | **2012 ($000)** | **2011 ($000)** |
| Therapeutics | $ 5,616 | $ 8,109 |
| Biosurgery | 2,419 | 1,811 |
| | $ 8,035 | $ 9,920 |

The decrease in research and development expenses in our Therapeutics segment in the first half of fiscal 2012 compared to the same period in fiscal 2011 reflects lower expenses in our acute myocardial infarction clinical trial, which was fully enrolled in the third quarter of 2011, resulting in lower patient and site costs since then and reduced activity in our Crohn s disease clinical trial. The increase in research and development expenses in our Biosurgery segment in fiscal 2012 when compared to the same period of fiscal 2011 reflects our increased process improvement efforts and development expenses incurred in exploring additional products to bring to market and the enrollment of the clinical trial required for to obtain cost reimbursement for Grafix.

*General and Administrative Expenses*

General and administrative expenses were $2.9 million for the six months ended June 30, 2012 compared to $5.0 million for the corresponding period in fiscal 2011. We incurred $753,000 of sales, general and administrative expenses related to our Biosurgery segment during the period, compared to $439,000 in the corresponding period of fiscal 2011. General and administrative expenses incurred in our Therapeutics segment during the first half of fiscal 2012 were $2.2 million compared to $4.5 million in the corresponding period of fiscal 2011, which included $1.7 million of non-cash compensation expense related to the extension of the expiration of a Warrant held by the chairman of our board of directors. The remaining decrease is the result of our continued cost cutting efforts and the refinement of many of our general business processes.

*Other Income, Net*

Other income, net, was $39,000 for the six months ended June 30, 2012, compared to $54,000 in the corresponding period in fiscal 2011. Our investments available for sale consist primarily of short-term, investment grade securities with a focus on avoiding market risk. We did not incur any interest expense in either 2012 or 2011.

*Benefit (Provision) for Income Taxes*

During the six months ended June 30, 2012, we trued-up our income tax receivable to the short-term deferred tax asset that was on our December 2011 balance sheet by recognizing a tax benefit of $32,000. Similarly, during the second fiscal quarter of 2011, we filed our fiscal 2010 income tax returns and recognized income tax expense of $43,000 when truing up our short-term deferred tax asset to the amounts reported in our fiscal 2010 income tax returns.

*Other Comprehensive (Loss) Income*

Our other comprehensive (loss) income consists of the unrealized gain or loss on our investments available for sale when they are marked-to-market at the end of each reporting period. During the first half of fiscal 2012, we recognized unrealized losses of $15,000 compared to unrealized gains of $34,000 during the comparable period of fiscal 2011.

**Liquidity and Capital Resources**

***Liquidity***

At June 30, 2012, we had $38.7 million in cash and investments available for sale. We have not had any outstanding debt at any time since fiscal 2008. Although there can be no assurance, we believe that we have sufficient liquidity on hand as of June 30, 2012 to fund our operations until we become cash flow positive through operations.

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***Cash Flows***

***Comparison of Six Months Ended June 30, 2012 and 2011***

Net cash used in operating activities for the six months ended June 30, 2012 was $8.5 million compared to $11.4 million in the corresponding fiscal period of the prior year. The 2012 net loss of $5.5 million was increased by the final amortization of deferred revenue, which was partially offset by $1.0 million of non-cash expenses and cash provided by other decreases in working capital. Net cash used in operating activities during 2011 reflect our net income of $5.8 million, which was offset primarily by reductions in deferred revenue and accounts payables and accrued expenses. Non-cash expenses incurred during the first quarter of 2011 were $3.1 million, which includes a $1.7 million charge related to the extension of the expiration date of our outstanding warrant.

Cash provided by investing activities during 2012 was $7.9 million compared to $11.5 million in 2011. Cash provided by investing activities during both fiscal periods was primarily the result of the net sales of investment available for sale in order to provide funds for operating activities.

***Capital Resources***

Our future capital requirements will depend on many factors, including:

- the scope and results of our research and preclinical development programs;

- the scope and results of our clinical trials, particularly regarding the number of patients required for our Phase 3 trials;

- the timing of and the costs involved in obtaining regulatory approvals for our biologic drug candidates, which could be more lengthy or complex than obtaining approval for a new conventional drug, given the FDA s limited experience with late-stage clinical trials and marketing approval for stem cell therapeutics;

- the costs of maintaining, expanding and protecting our intellectual property portfolio, including possible litigation costs and liabilities; and

- the costs of expanding our work force consistent with expanding our business and operations.

**Off-Balance Sheet Arrangements.**

We have no off-balance sheet financing arrangements and we have not entered into any transactions involving unconsolidated subsidiaries or special purpose entities.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk** .

*Interest Rate Risk*

Due to the short duration of our investment portfolio and the high quality of our investments, an immediate 10% change in interest rates would not have a material effect on the value of our portfolio. Therefore, we would not expect our operating results or cash flows to be affected to any material degree by the effect of a sudden change in market interest rates on our securities portfolio.

We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectability and establishment of appropriate allowances in connection with our internal controls and policies.

*Foreign Currency Exchange Rate Risk*

We conduct clinical trial activities in areas that operate in a functional currency other than the United States dollar (USD). As a result, when the USD rises and falls against the functional currencies of these other nations, our costs will either increase or decrease by the relative change in the exchange rate. Foreign currency gains and losses were not significant during the six months ended June 30, 2012 or 2011, and at the present time, we have elected not to hedge our exposure to foreign currency fluctuations.

*Derivative Instruments*

We do not enter into hedging or derivative instrument arrangements.

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**Item 4. Controls and Procedures.**

***Evaluation of Disclosure Controls and Procedures.*** An evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Quarterly Report on Form 10-Q was made under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (a) are effective to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is timely recorded, processed, summarized and reported and (b) include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

***Changes in Internal Control over Financial Reporting.*** There have not been any changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II - OTHER INFORMATION**

**Item 1. Legal Proceedings**.

From time to time, we receive threats or may be subject to routine litigation matters related to our business. However, we are not currently a party to any material pending legal proceedings.

**Item 1A. Risk Factors**.

There have not been any material changes in the risk factors previously disclosed under the heading Risk Factors in Part I Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 as filed with the Securities and Exchange Commission on March 14, 2012.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**.

None.

**Item 3.** **Defaults Upon Senior Securities**.

None.

**Item 4.** **Mine Safety Disclosures.**

None.

**Item 5.** **Other Information**.

None.

**Item 6.** **Exhibits.**

| Exhibit Number | Description of Exhibit |
|---|---|
| 31.1.1* | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002). |
| 31.2.1* | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002). |
| 32.1* | Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101 | *The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, formatted in Extensible Business Reporting Language (XBRL), include: (i) the Condensed Statements of Income, (ii) the Condensed Balance Sheets, (iii) the Condensed Statements of Cash Flows, and (iv) related notes (furnished herewith).* |

* filed herewith.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**Osiris Therapeutics, Inc.**

Date: August 9, 2012

/s/ PHILIP R. JACOBY, JR.
Philip R. Jacoby, Jr.
Chief Financial Officer (Principal Financial Officer)

Date: August 9, 2012

/s/ MATTHEW NEUMAYER
Matthew Neumayer
Corporate Controller (Principal Accounting Officer)